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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,889	01/21/2004	Shubh D. Sharma	70025-US04-139	4237

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PALATIN TECHNOLOGIES, INC.
4-C CEDAR BROOK DRIVE
CEDAR BROOK CORPORATE CENTER
CRANBURY, NJ 08512

EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,889	SHARMA ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-56 are pending.

2. The applicant is respectfully invited to note that claims 1-56 are listed as Groups I, etc., and II, etc., but in actuality, contain within those claims a **large number of separate and distinct inventions**. Election of a *single invention* from within this group of claims is required as specifically set forth (see Further Restriction, below).

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I, etc. Claims 1-49, drawn to a compound having the structure of formula I, as in claim 1, classifiable in class 514, subclass 249.

II, etc. Claims 50-56, drawn to a method of altering a disorder or condition associated with the activity of a melanocortin receptor, comprising administering to a patient a therapeutically effective amount of the composition of claim 49 (i.e., a composition of "any of the foregoing structure"), classified in class 514, subclass 19.

Further Restriction

A) In addition each of Groups I, etc. and II, etc. (methods and compounds having the structure of formula I, as in claim 1) detailed above reads on patentably distinct Groups. Groups I, etc. and II, etc., are further divided into multiple groups each representing a different molecular core ring structure. The compounds within each Group comprise a different core ring structure that has no unifying structural relationship with the other drug cores, that results in a shared functional property among the plurality of core ring structures. Thus a further restriction is applied to each of Groups I, etc., and II, etc.

The inventions are distinct, each from the other because of the following reasons:

The claims of Group I, etc., and II, etc., are explicitly drawn to compounds with different ring structures, particularly as follows: **J** is a ring structure selected from the group consisting of substituted or unsubstituted aromatic carbocyclic rings, substituted or unsubstituted non-aromatic carbocyclic rings, substituted or unsubstituted aromatic fused carbobicyclic ring groups, substituted or unsubstituted aromatic carbocyclic ring groups wherein the rings are joined by a bond or --O--, and substituted or unsubstituted aromatic fused heterobicyclic ring groups; wherein in each instance the rings comprise 5 or 6 ring atoms. **W** is a heteroatom unit with

at least one cationic center, hydrogen bond donor or hydrogen bond acceptor wherein at least one atom is N, and wherein **W** encompasses ring structures, as exemplified in claim 7. **Q** is defined to be an aromatic carbocyclic ring selected that is phenyl, substituted phenyl, napthyl, or substituted napthyl. The compound of the claims has a different molecular core ring structure, depending upon the value given **z**. Thus the formula embraces numerous molecular structures with different core ring structures. The elected compound must provide values for the variables for **J**, **W**, **Q**, and **z**, which define the elected core ring structure.

If one of Groups I, etc., or II, etc., is elected, the elected **further restricted Group** *must* result in a single specific generic compound, *i.e.*, a product comprising a single molecular core ring structure. If an Invention of Groups I, etc., or II, etc., is elected, a specific molecular structure must be elected as a species, (see below requirement for election of species).

For this response to be complete, applicants should provide the structure of the elected core ring structure and list all of the claims readable upon the elected core.

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each product is assumed to be a patentably distinct invention, absent evidence to the contrary.

The Inventions I, etc., and II, etc., are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process may be practiced with known antagonists for melanocortin, such as alpha melanocyte stimulating hormone (as taught by Adan et al., European J. Pharmacology, Section 269 (1994), pp. 331-337, IDS filed 10/12/2004).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
>
> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

5. This application contains claims directed to the following patentably distinct species of the claimed invention: Optional particular substituents on a specific molecular core ring structures.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Groups I, etc. and II, etc., (claims 1-56), are generic.

6. This application contains claims directed to the following patentably distinct species: A specific disorder or condition. The species are independent or distinct because the different disorders or condition have different etiologies and so have materially different mode of operation, function and effect. Applicant should indicate how the claims of Group II, etc., read on the elected species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 50, 51, 54 are generic.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. For this response to be complete and for search purposes, applicants should provide the ***chemical structure of elected compounds species***, wherein the specific formula substituents of the above identified elected species is defined, either by picture or by expressing the species in terms of the variables of the formula. Thus, applicant should provide, for search purposes, a chemical structure of a particular elected distinct species claimed, defined as to atom and bond; and a molecular core ring structure for the Invention of the Group elected, as required above in the instant Requirement for Restriction/Election. The provided chemical structure of the elected species must depict a single molecule, from which a search is to commence.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark L. Shibuya
Examiner
Art Unit 1639